SYNTHES®

K120807 #1/1

## 3.0 510(k) Summary

**Sponsor:** Synthes (USA)
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JUL 6 2012

**Date Prepared:** March 15, 2012

**Device Name:** Synthes MultiLoc Humeral Nailing System

**Classification:** Class II, §888.3020 – Intramedullary fixation rod
Product Code: HSB

**Predicate Device:**

| | |
|---|---|
| Synthes Cannulated Titanium Humeral Nail System | (K033071) |
| Synthes MultiLoc Proximal Humeral Nailing System | (K103002) |
| Synthes Angular Stable Locking System [ASLS] | (K090241) |
| Synthes 4.0mm and 5.0mm Locking Screws | (K000089) |
| Synthes 3.5mm Locking Screws | (K000684) |

**Device Description:** The Synthes MultiLoc Humeral Nailing System consists of metallic rods and accessories which are intended for implantation in the medullary canal of the humerus for fracture fixation.

The system features intramedullary nail devices, as well as bone screws and end cap accessories. The nails are cannulated, offered in 7.0mm, 8.5mm, and 10mm diameters, and are available in 180mm – 315mm in overall length. The nails additionally feature a polymer inlay in the proximal end to enhance the stability of the 4.5mm MultiLoc locking screws. Cleared 4.5mm MultiLoc Screws, used to facilitate the proximal locking of the nail construct, can be interlocked with cleared Synthes 3.5mm Locking Screws to enhance the stability of the construct.

**Indications for use:** The Synthes MultiLoc Humeral Nailing System is indicated for fractures of the proximal humerus, including 2-part surgical neck fractures, 3-part fractures, and 4-part fractures, proximal humeral fractures with diaphyseal extension, diaphyseal fractures of the humeral shaft, and impending pathologic humeral fractures.

**Substantial Equivalence:** Information presented supports substantial equivalence of the Synthes MultiLoc Humeral Nail to the predicate devices. The proposed system has the same indications for use, is similar in design, incorporates the same fundamental product technology and is composed of the same materials.

To additionally support substantial equivalence, testing comparing the bending strength of the subject and predicate devices was performed according to ASTM F 1264-03. *In vitro* bench testing included static and dynamic 4-point bending, torsional strength, and eccentric dynamic fatigue strength of the construct, compared to the predicate devices. Results support substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Synthes (USA)
% Ms. Rebecca Blank
Associate Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

JUL 6 2012

Re: K120807
Trade/Device Name: Synthes MultiLoc Humeral Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: June 5, 2012
Received: June 6, 2012

Dear Ms. Blank:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

## 2.0 Indications for Use

510(k) Number (if known): K120807

Device Name: Synthes MultiLoc Humeral Nailing System

Indications for Use:

The Synthes MultiLoc Humeral Nailing System is indicated for fractures of the proximal humerus, including 2-part surgical neck fractures, 3-part fractures, and 4-part fractures, proximal humeral fractures with diaphyseal extension, diaphyseal fractures of the humeral shaft, and impending pathologic humeral fractures.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K120807